REMARKS

This paper is being presented in response to the non-final official action dated September 20, 2005, wherein: **(a)** claims 41 and 44-51 are pending; **(b)** the pending claims have been rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-14 of Wong et al. U.S. Patent No. 6,610,690; **(c)** the pending claims have been rejected under 35 USC § 112, ¶ 2, as being indefinite; and, **(d)** claims 41 and 44-49 have been rejected under 35 USC § 102(b) as being anticipated by G.D. Burrows et al., "Antidepressant Efficacy and Tolerability of the Selective Norepinephrine Reuptake Inhibitor Reboxetine: A Review," J. Clin. Psychiatry, vol. 59, Suppl. 14, 4 pages (1998) (the "Burrows publication"). Reconsideration and withdrawal of the rejections are respectfully requested in view of the foregoing amendments and following remarks.

This paper is timely filed as it is accompanied by a petition under 37 CFR § 1.136(a) for an extension of time to file in the second month, and payment of the required extension fee.

I. Brief Summary of the Amendments

A. Amendments to the Specification

The specification has been amended to update the cross-reference to related applications.

The "Abstract of the Disclosure" has been amended pursuant to the statements set forth at page 2 of the action, and now reads:

> Disclosed herein are methods of treating an individual suffering from fibromyalgia and other somatoform disorders. The methods generally include administration of a therapeutic amount of racemic reboxetine, or a pharmaceutically acceptable salt thereof, to the individual.

No new matter has been introduced by these amendments.

B. Amendments to the Claims

Claims 41, 44-48, and 50 have been amended herein. Specifically, independent claim 41 has been amended to more clearly specify that the recited treatment methods are directed to an individual suffering from fibromyalgia and other somatoform disorders, and that the method includes administering to the individual a therapeutically effective "amount" of racemic reboxetine, or a pharmaceutically acceptable salt thereof. Support for the amendment can be found in the specification, which states:

> Mental and neurological disorders that may be treated or prevented by administration of a therapeutically effective amount of a racemic reboxetine (or a derivative or

> pharmaceutically acceptable salts thereof) include, but are not limited to ... fibromyalgia and other somatoform disorders (including somatization disorder, conversion disorder, pain disorder, hypochondriasis, body dysmorphic disorder, undifferentiated somatoform disorder, and somatoform NOS) ....

See the specification at page 27, lines 3-6 and 13-16.

Dependent claims 44-46 have been amended to clarify that racemic reboxetine, or a pharmaceutically acceptable salt thereof, is administered in the recited amounts. Dependent claim 47 has been amended to recite that racemic reboxetine, or a pharmaceutically acceptable salt thereof, is administered as a composition, and the composition is administered orally, parenterally, topically, transdermally, rectally, or vaginally. Support for the amendments to these claims can be found in the specification at, for example, page 28, lines 16-23.

Dependent claim 48 has been amended to recite the composition is orally administered, and that the composition also includes a pharmaceutically acceptable carrier comprising at least one of a binder, diluent, lubricant, disintegrating agent, effervescing agent, dyestuff, sweetener, and wetting agent. Support for the amendment can be found in the specification at, for example, page 23, line 7, to page 24, line 11.

Dependent claim 50 has been amended to correct typographical errors in the spelling of the terms "parenterally" and "intravenously." Claim 50 also has been amended to specify that the composition is parenterally administered. Support for the amendment can be found in the specification at, for example, page 28, lines 21-23.

Dependent claim 54 has been newly added and recites that other somatoform disorders include one or more of a somatization disorder, a conversion disorder, a pain disorder, hypochondriasis, a body dysmorphic disorder, an undifferentiated somatoform disorder, and somatoform NOS. Support for the new claim can be found in canceled claim 27 of the application as originally filed, and also at page 27, lines 3-6 and 13-16.

No new matter has been introduced by these amendments.

II. The Obviousness-Type Double Patenting Rejection

The pending claims have been rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-14 of Wong et al. U.S. Patent No. 6,610,690:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the claims of the ['690] patent encompasses that of the instant claims.

See p. 2 of the action. The rejection is traversed, and reconsideration and withdrawal of the rejection are respectfully requested in view of the response provided below.

A. Proper Basis for an Obviousness-Type Double Patenting Rejection

Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention to a statutorily-prescribed term. 35 USC § 154(a)(2). Non-statutory, or "obviousness-type," double patenting is a doctrine judicially created to prevent claims in separate patent applications or patents from issuing where those claims do not recite the "same" invention, but nonetheless claim inventions so alike that granting both inventions exclusive rights would effectively extend patent protection beyond the statutorily-prescribed term. *See generally, Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001); *see also Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed. Cir. 1990); *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985) (explaining that, even though no explicit statutory basis exists for obviousness-type double patenting, the doctrine is necessary to prevent a patent term extension through claims in a second patent that are patentably indistinct from those in the first patent).

An obviousness-type double patenting analysis is "analogous to [a failure to meet] the nonobviousness requirement of 35 USC § 103" except that the specification of the patent principally underlying the double patenting rejection cannot be considered prior art. *See* MPEP §804(II)(B)(1) (8th ed., rev. 3, Aug. 2005); *see also, General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279 (Fed. Cir. 1992) (stating that the disclosure of the patent principally underlying the rejection may not be used as prior art). During prosecution, therefore, the U.S. Patent and Trademark Office (PTO) bears the burden of establishing a *prima facie* case that the application claims are obvious over the claims in a commonly-assigned patent. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988) (stating that the PTO "has the burden under § 103 to establish a *prima facie* case of obviousness"). The PTO's conclusion of obviousness-type double patenting must be made in light of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

Generally, an obviousness-type double patenting rejection should make clear: (a) the differences between the inventions defined by the conflicting claims; and, (b) reasons why a person having ordinary skill in the art would conclude the invention recited in the application claims would have been an obvious variation of (i.e., patentably indistinct from) the invention recited in the earlier patent claims. *See generally*, MPEP § 804(II)(B)(1); *see also, Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326-27 (Fed. Cir. 1999). An application claim is patentably indistinct from an earlier patent claim if the application claim is obvious over (or anticipated by) the earlier patent claim. *In re Longi*, 759 F.2d at 896 (affirming a holding of obviousness-type double patenting because the claims at issue were obvious over claims in four prior art patents); *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998)

(affirming a holding of obviousness-type double patenting where a patent application claim to a genus is anticipated by a patent claim to a species within that genus).

B. The Obviousness-Type Double Patenting Rejection Is Traversed

The action does not set forth a *prima facie* case demonstrating that claims 1-14 of the '690 patent either anticipate or render obvious the pending claims in this application. Specifically, the action does not (construe or) compare any of claims 1-14 of the '690 patent to any of the rejected claims, other than to conclude that "the subject matter of the claims of the ['690] patent encompasses that of the instant claims." Furthermore, the action neither identifies the differences between claims 1-14 of the '690 patent and the rejected claims, nor how those differences are such that the rejected claims are nevertheless obvious over claims 1-14 of the '690 patent. Consequently, and on this basis alone, the applicants respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

Notwithstanding whether a *prima facie* case of obviousness is set forth in the action, claims 1-14 of the '690 patent neither anticipate nor render obvious any of the rejected claims.

This application and the application that issued as the '690 patent are commonly-assigned and related to one another. Specifically, this application is a division of U.S. patent application Serial No. 10/255,450 filed September 26, 2002, now abandoned, which is a division of U.S. patent application Serial No. 09/599,213 filed June 22, 2000, now U.S. Patent No. 6,465,458 issued October 15, 2002. The '690 patent issued from U.S. patent application No. 10/037,344 filed January 4, 2002, which is a division of the '213 application. Thus, the present application and the application from which the '690 patent issued both claim priority to the '213 application and disclose identical subject matter.

During prosecution of the '213 application, the PTO issued an official action dated August 21, 2001, requiring the applicants "to elect a single disclosed species (i.e. a compound and a condition to be treated)." In response to that action, the applicants elected claims reciting an optically pure (S,S) reboxetine for the treatment of chronic pain. In contrast to the '213 application (the '458 patent), the present application includes claims reciting methods of treating an individual suffering from fibromyalgia and other somatoform disorders **with racemic reboxetine**. For example, independent claim 41 (as amended herein) of this application recites:

> A method of treating an individual suffering from fibromyalgia and other somatoform disorders, the method comprising the step of administering to the individual a therapeutically effective amount of racemic reboxetine or a pharmaceutically acceptable salt thereof.

Dependent claims 44-51 and 54 of this application recite additional features of the method. In contrast to this application, the '690 patent and claims 1-14 therein recite methods of treating

an individual suffering from fibromyalgia and other somatoform disorders **with a composition comprising a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000**. For example, independent claim 1 of the '690 patent recites

> A method of treating an individual suffering from fibromyalgia and other somatoform disorders, the method comprising the step of administering to the individual a therapeutically effective amount of a composition comprising a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000.

See the '690 patent at col. 18, lines 60-65. Dependent claims 2-14 of the '690 patent recite additional features of that method.

This application and the '690 patent (which share the same disclosure) clearly indicate that racemic reboxetine is **not** a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000; instead, racemic reboxetine has a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of 81:

> The K_i values calculated according to the Cheng-Prassoff equation are provided in the table below:

TABLE

Compound	Norepinephrine Reuptake (K_i nM)	Serotonin Reuptake (K_i nM)	Selectivity of K_i of Serotonin/ Norepinphrine
(S,S) Reboxetine	0.23 ± 0.06	2937 ± 246	12,770
(R,R) Reboxetine	7.0 ± 1.7	104 ± 43	15
Reboxetine	1.6 ± 0.6	129 ± 13	81

> The data shows that (S,S) reboxetine is about five to about eight fold more potent than the reboxetine racemate with respect to inhibiting the reuptake of norepinephrine. In addition, racemic reboxetine has an 81 fold selectivity favoring norepinephrine reuptake inhibition over serontonin reuptake inhibition.

See the specification at p. 31, lines 8-17 (Table I); *see also* the '690 patent at col. 17, line 57, to col. 18, line 9.

Thus, at least one difference between the pending claims and claims 1-14 of the '690 patent is that the pending claims recite a method utilizing racemic reboxetine, while claims 1-14 of the '690 patent recite a method utilizing a compound having a specific selectivity **not**

possessed by racemic reboxetine. The action identifies no prior art suggesting that the disclosure of a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000 is equivalent to (or a variant of) a disclosure of racemic reboxetine. Furthermore, even if such prior art exists, the action identifies no evidence that a person having ordinary skill in the art would have been motivated to substitute racemic reboxetine in the place of a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000. Still further, even if such prior art exists and even if the skilled artisan would have been motivated to make the substitution, the action identifies no evidence that the skilled artisan would have a reasonable expectation of success.

Consequently, the differences between the subject matter recited in the pending claims and that recited in claims 1-14 of the '690 patent are such that the pending claims are neither anticipated by nor rendered obvious over claims 1-14 of the '690 patent (alone or in combination with the prior art). Accordingly, reconsideration and withdrawal of the obviousness-type double patenting rejection are respectfully requested on grounds that the pending claims are neither anticipated by nor rendered obvious over claims 1-14 of the '690 patent (alone or in combination with the prior art).

III. The 35 USC § 112, ¶ 2, Rejection

The pending claims have been rejected under 35 USC § 112, ¶ 2, as being indefinite. *See* p. 3 of the action. According to the action:

> The metes and bounds of "and other somatoform disorders" cannot be precisely determined. The specification provides no clear definition, only examples. Applicants should recite those disorders contemplated.

Id. Reconsideration and withdrawal of the rejection are respectfully requested.

A. Proper Basis for a § 112, ¶ 2, Rejection

When examining a claim for compliance with § 112, ¶ 2, the PTO must consider the claim as a whole to determine whether the claim apprises a hypothetical person having ordinary skill in the art of its scope and, therefore, provides a clear warning to others as to what constitutes an infringement of the claim. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000). Claim definiteness is not analyzed in a vacuum; instead, it is analyzed in light of the application's complete disclosure, the teachings of the prior art, and the interpretation the hypothetical person having ordinary skill in the pertinent art would attribute the claim at the time the invention was made. *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971). The analysis "focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the

specification." *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). According to the MPEP:

> The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 USC § 112, first paragraph with respect to the claimed invention.

MPEP § 2173.02 (8th ed., rev. 3, Aug. 2005). The MPEP also states that the meaning of every term recited in a claim should be apparent from "the prior art or from the specification and drawings at the time the application is filed." MPEP § 2173.05(a)(I).

B. The § 112, ¶ 2, Rejection Is Traversed

Recitation of "and other somatoform disorders" in the pending claims is definite and, therefore, the pending claims are compliant with § 112, ¶ 2.

The level of skill in the art is generally that of a Ph.D. or M.D. with expertise in the area of neurology. An example of a Ph.D. with expertise in the area of neurology is a person having a Ph.D. in pharmacology and experience in the neurosciences

The hypothetical person having ordinary skill in the art would have readily understood the metes and bounds of the term as of the July 1, 1999, priority date of this application. Specifically, appended hereto are portions of the "American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*," 376-77 and 485 (4th Ed., American Psychiatric Association, Washington, D.C., 1994) (hereinafter the "DSM-IV"), which is a standard textbook commonly referenced by those skilled in the art, and which describes somatoform disorders as follows:

> The common feature of the Somatoform Disorders is the presence of physical symptoms that suggest a general medical condition (hence, the term *somatoform*) and are not fully explained by a general medical condition, by the direct effects of a substance, or by another mental disorder (e.g., Panic Disorder). The symptoms must cause clinically significant distress or impairment in social, occupational, or other areas of functioning. In contrast to Factitious Disorders and Malingering, the physical symptoms are not intentional (i.e., under voluntary control). Somatoform Disorders differ from Psychological Factors affecting Medical Condition in that there is no diagnosable general medical condition to fully account for the physical symptoms. The grouping of these disorders in a single section is based on clinical utility (i.e., the need to exclude occult general medical conditions or substance-induced etiologies for the bodily symptoms) rather than on assumptions regarding shared etiology or

> mechanism. These disorders are often encountered in general medical settings.

The DSM-IV at 485. The DSM-IV proceeds to identify examples of somatoform disorders as including: somatization disorder, undifferentiated somatoform disorder, conversion disorder, pain disorder, hypochondriasis, body dysmorphic disorder, and somatoform disorder NOS (i.e., Not Otherwise Specified). *Id.*

The specification (at page 27, lines 3-6 and 13-16) also describes treating somatoform disorders, and identifies (consistent with the DSM-IV) as examples of such disorders: somatization disorder, undifferentiated somatoform disorder, conversion disorder, pain disorder, hypochondriasis, body dysmorphic disorder, and somatoform disorder NOS.

In view of the application's complete disclosure (which describes methods of treating somatoform disorders and examples of such disorders) and the teachings set forth in the DSM-IV (published in 1994), it is respectfully submitted that the hypothetical person having ordinary skill in the art would have understood the scope of "somatoform disorders" and the metes and bounds of the claimed invention as of the July 1, 1999, priority date of this application. Consequently, it is respectfully submitted that the pending claims are sufficiently clear and definite under § 112, ¶ 2, such that the rejection, upon reconsideration, should be withdrawn.

IV. The 35 USC § 102(b) Rejection

Claims 41 and 44-49 have been rejected under 35 USC § 102(b) as being anticipated by G.D. Burrows et al., "Antidepressant Efficacy and Tolerability of the Selective Norepinephrine Reuptake Inhibitor Reboxetine: A Review," J. Clin. Psychiatry, vol. 59, Suppl. 14, 4 pages (1998) (hereinafter, the "Burrows publication"). *See* p. 3 of the action. Reconsideration and withdrawal of the rejection are respectfully requested in view of the response provided below.

A. Proper Basis for a § 102(b) Rejection

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Thus, a determination that a claim is anticipated under 35 USC § 102 involves two analytical steps. First, the U.S. Patent and Trademark Office (PTO) must interpret the claim language, where necessary, to ascertain its meaning and scope. In interpreting the claim language, the PTO is permitted to attribute to the claims only their broadest *reasonable* meaning as understood by persons having ordinary skill in the art, considered in view of the entire disclosure of the specification. *See In re Morris*, 127 F.3d 1048, 1054(Fed. Cir. 1997). Second, the PTO must compare the construed claim to a single prior art reference and set forth factual findings that

"each and every limitation is found either expressly or inherently [disclosed] in [that] single prior art reference." *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360(Fed. Cir. 1998). Additionally, "[t]he identical invention must be shown in as complete detail as is contained in the patent claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

B. The § 102(b) Rejection Is Traversed

According to the action, claims 41 and 44-49 are anticipated by the Burrows publication because:

> Burrows teaches the administration of racemic reboxetine to treat dysthymia, a chronic disturbance of mood characterized by recurrent periods of depression, insomnia and pessimism. Dysthmia [*sic*, Dysthymia] may be considered a somatoform disorder in that there is no organic basis or known physical cause. See page 5, column one, where oral dosages as those required by instant claims 44-49 are disclosed.

See p. 3 of the action. It is respectfully submitted that the pending claims are not anticipated by the Burrows publication.

The Burrows publication describes the treatment of major depressive disorder ("MDD") and dysthymia with racemic reboxetine. However, the position set forth in the action (i.e., that "Dysthmia [*sic*, Dysthymia] may be considered a somatoform disorder in that there is no organic basis or known physical cause") lacks any scientific support. Both MDD and dysthymia are forms of *depressive* disorder. It is on this basis that racemic reboxetine—an **established antidepressant**—is effective in the treatment of these conditions. In contrast, however, the very essence of somatoform disorders is the presence of **somatic** symptoms in the absence of identifiable underlying organic pathology where the clinician judges that the onset, severity, and duration of somatic symptoms (e.g., pain, gastrointestinal disturbance) are strongly linked to psychological factors.

The diagnostic categories of MDD and dysthymia are distinct nosological entities within the framework of DSM-IV. A diagnosis of dysthymia cannot be subsumed under the heading of somatoform disorders because somatoform disorders are only diagnosed when psychiatric examination has excluded other mental disorders (including dysthymia). See, for example, pages 376-77 of DSM-IV, appended hereto for further evidence of the diagnostic feature of dysthymia. The position set forth in the action (i.e., that "Dysthmia [*sic*, Dysthymia] may be considered a somatoform disorder in that there is no organic basis or known physical cause") is not only unsupported by scientific evidence, but also contradicted by scientific evidence.

It also would not have been obvious to a person having ordinary skill in the art as of the priority date of this application to treat an individual suffering from fibromyalgia or another

somatoform disorders with racemic reboxetine simply on the basis that racemic reboxetine had been used to treat individuals suffering from MDD and dysthymia. Symptoms of fibromyalgia include widespread and diffuse pain and tenderness. At the time of the Burrows publication, there was no *a priori* reason to predict the analgesic properties of reboxetine in fibromyalgia, with a reasonable expectation of success. Furthermore, a person having ordinary skill in the art would not have then (or now) considered fibromyalgia to be a form of mental disorder; but, rather as a condition representing a state of central sensitization or hypersensitivity within pain pathways. Accordingly, not only does the Burrows publication fail to anticipate the pending claims it also would not have rendered obvious those claims obvious even when considered with other teachings in the art.

Accordingly, reconsideration and withdrawal of the § 102(b) rejection are respectfully requested.

CONCLUSION

In view of the foregoing, entry of amendments to the specification, entry of new claim 54, entry of the amendments to claims 41, 44-48, and 50, reconsideration and withdrawal of the rejections, and allowance of all pending claims 41, 44-51, and 54 are respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to contact the undersigned attorney.

Respectfully submitted,

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APPENDIX

Copy of "American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*," 376-77 and 485 (4th Ed., American Psychiatric Association, Washington, D.C., 1994).

Manufactured in the United States of America on acid-free paper

American Psychiatric Association
1400 K Street, N.W., Washington, DC 20005

The correct citation for this book is American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition. Washington, DC, American Psychiatric Association, 1994.

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Diagnostic criteria for 296.3x Major Depressive Disorder, Recurrent

A. Presence of two or more Major Depressive Episodes (see p. 356).

Note: To be considered separate episodes, there must be an interval of 2 consecutive months in which criteria are not met for a Major Depressive E

B. The Major Depressive Episodes are not better accounted for by Schizoaffect order and are not superimposed on Schizophrenia, Schizophreniform Disord lusional Disorder, or Psychotic Disorder Not Otherwise Specified.

C. There has never been a Manic Episode (see p. 362), a Mixed Episode (see p. 36 a Hypomanic Episode (see p. 368). **Note:** This exclusion does not apply if all o manic-like, mixed-like, or hypomanic-like episodes are substance or treatmen duced or are due to the direct physiological effects of a general medical conditio

If the full criteria are currently met for a Major Depressive Episode, *specify* its curr clinical status and/or features:

Mild, Moderate, Severe Without Psychotic Features/ Severe With Psychotic Features (see p. 411)
Chronic (see p. 417)
With Catatonic Features (see p. 417)
With Melancholic Features (see p. 419)
With Atypical Features (see p. 420)
With Postpartum Onset (see p. 422)

If the full criteria are not currently met for a Major Depressive Episode, *specify* the current clinical status of the Major Depressive Disorder or features of the most recent episode:

In Partial Remission, In Full Remission (see p. 411)
Chronic (see p. 417)
With Catatonic Features (see p. 417)
With Melancholic Features (see p. 419)
With Atypical Features (see p. 420)
With Postpartum Onset (see p. 422)

Specify:

Longitudinal Course Specifiers (With and Without Interepisode Recovery) (see p. 424)
With Seasonal Pattern (see p. 425)

300.4 Dysthymic Disorder

Diagnostic Features

The essential feature of Dysthymic Disorder is a chronically depressed mood that occurs for most of the day more days than not for at least 2 years (Criterion A). Individ-

h Dysthymic Disorder describe their mood as sad or "down in the dumps." dren, the mood may be irritable rather than depressed, and the required mini- duration is only 1 year. During periods of depressed mood, at least two of the ving additional symptoms are present: poor appetite or overeating, insomnia or somnia, low energy or fatigue, low self-esteem, poor concentration or difficulty ng decisions, and feelings of hopelessness (Criterion B). Individuals may note the minent presence of low interest and self-criticism, often seeing themselves as un- esting or incapable. Because these symptoms have become so much a part of the ividual's day-to-day experience (e.g., "I've always been this way," "That's just how m"), they are often not reported unless directly asked about by the interviewer. During the 2-year period (1 year for children or adolescents), any symptom-free in- rvals last no longer than 2 months (Criterion C). The diagnosis of Dysthymic Dis- der can be made only if the initial 2-year period of dysthymic symptoms is free of Major Depressive Episodes (Criterion D). If the chronic depressive symptoms include Major Depressive Episode during the initial 2 years, then the diagnosis is Major De- pressive Disorder, Chronic (if full criteria for a Major Depressive Episode are met), or Major Depressive Disorder, In Partial Remission (if full criteria for a Major Depres- ive Episode are not currently met). After the initial 2 years of the Dysthymic Dis- order, Major Depressive Episodes may be superimposed on the Dysthymic Disorder. In such cases ("double depression"), both Major Depressive Disorder and Dysthymic Disorder are diagnosed. Once the person returns to a dysthymic baseline (i.e., criteria for a Major Depressive Episode are no longer met but dysthymic symptoms persist), only Dysthymic Disorder is diagnosed.

The diagnosis of Dysthymic Disorder is not made if the individual has ever had a Manic Episode (p. 357), a Mixed Episode (p. 362), or a Hypomanic Episode (p. 365) or if criteria have ever been met for Cyclothymic Disorder (Criterion E). A separate diagnosis of Dysthymic Disorder is not made if the depressive symptoms occur exclusively during the course of a chronic Psychotic Disorder, such as Schizophrenia or Delusional Disorder (Criterion F), in which case they are regarded as associated features of these disorders. Dysthymic Disorder is also not diagnosed if the disturbance is due to the direct physiological effects of a substance (e.g., alcohol, antihypertensive medications) or a general medical condition (e.g., hypothyroidism, Alzheimer's disease) (Criterion G). The symptoms must cause clinically significant distress or impairment in social, occupational (or academic), or other important areas of functioning (Criterion H).

Specifiers

Age at onset and the characteristic pattern of symptoms in Dysthymic Disorder may be indicated by using the following specifiers:

Early Onset. This specifier should be used if the onset of the dysthymic symptoms occurs before age 21 years. Such individuals are more likely to develop subsequent Major Depressive Episodes.

Late Onset. This specifier should be used if the onset of the dysthymic symptoms occurs at age 21 or older.

With Atypical Features. This specifier should be used if the pattern of symp-

Somatoform Disorders

The common feature of the Somatoform Disorders is the presence of physical symptoms that suggest a general medical condition (hence, the term *somatoform*) and are not fully explained by a general medical condition, by the direct effects of a substance, or by another mental disorder (e.g., Panic Disorder). The symptoms must cause clinically significant distress or impairment in social, occupational, or other areas of functioning. In contrast to Factitious Disorders and Malingering, the physical symptoms are not intentional (i.e., under voluntary control). Somatoform Disorders differ from Psychological Factors Affecting Medical Condition in that there is no diagnosable general medical condition to fully account for the physical symptoms. The grouping of these disorders in a single section is based on clinical utility (i.e., the need to exclude occult general medical conditions or substance-induced etiologies for the bodily symptoms) rather than on assumptions regarding shared etiology or mechanism. These disorders are often encountered in general medical settings.

The following Somatoform Disorders are included in this section:

Somatization Disorder (historically referred to as hysteria or Briquet's syndrome) is a polysymptomatic disorder that begins before age 30 years, extends over a period of years, and is characterized by a combination of pain, gastrointestinal, sexual, and pseudoneurological symptoms.

Undifferentiated Somatoform Disorder is characterized by unexplained physical complaints, lasting at least 6 months, that are below the threshold for a diagnosis of Somatization Disorder.

Conversion Disorder involves unexplained symptoms or deficits affecting voluntary motor or sensory function that suggest a neurological or other general medical condition. Psychological factors are judged to be associated with the symptoms or deficits.

Pain Disorder is characterized by pain as the predominant focus of clinical attention. In addition, psychological factors are judged to have an important role in its onset, severity, exacerbation, or maintenance.

Hypochondriasis is the preoccupation with the fear of having, or the idea that one has, a serious disease based on the person's misinterpretation of bodily symptoms or bodily functions.

Body Dysmorphic Disorder is the preoccupation with an imagined or exaggerated defect in physical appearance.

Somatoform Disorder Not Otherwise Specified is included for coding disorders with somatoform symptoms that do not meet the criteria for any of the specific Somatoform Disorders.